Mylan
Better Health for a Better World

To: Office of Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

From: Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505

Date: November 17, 2020

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on October 23, 2020 Mylan Pharmaceuticals Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new generic prescription drug, Budesonide ER 9mg tablets, ("the Product"), to the commercial market on October 20, 2020 at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program.

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Product. Mylan notes that the Office of the Attorney General has not yet prescribed a format for submissions under this section. Further, as authorized by 18 V.S.A. § 4637(d), Mylan has limited the information reported to that which is in the public domain or publicly available.

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

Budesonide ER 9mg tablets are indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
00378-4500-93	Budesonide ER Tablets, 9mg	30	$1,549.02

The prices negotiated with customers as well as any marketing plans in the United States or internationally are confidential and not in the public domain or publicly available. In the United States, Mylan sells its products directly to wholesalers, distributors, retail pharmacy chains, long-term care facilities and mail order pharmacies. Mylan also sells its generic products indirectly to several entities, including independent pharmacies, managed care organizations, hospitals, etc. These customers, called "indirect customers," purchase our products primarily through our wholesale customers.

(2) the estimated volume of patients who may be prescribed the drug;

No information specific to the estimated number of patients that may be prescribed Mylan's Product is in the public domain or publicly available.

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

The Product was granted priority review by the FDA.

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

The Product was not the result of an acquisition.